

### **REMARKS**

Of claims 1-67 which were contained in the pending application, claims 7, 9, 14, and 67 are now canceled. Claim 1 has been amended to incorporate the limitations of now-canceled claims 7, 9 and 14. As such, no new matter is introduced as a result of this amendment. In addition, claims 8 and 16 have been amended to correct the informalities noted by the Examiner. No new matter is introduced as a result of these amendments.

### **Rejections Under 35 U.S.C. §112**

The Examiner has rejected claims 47, 48 and 67 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

In making this rejection, the Examiner states that there is no antecedent basis in claim 1 for “the biodegradable polymer” (claim 47, line 2). Claim 47 has since been amended to recite “one of the at least two biodegradable polymers.” No new matter is introduced as a result of this amendment.

The Examiner also states that there is no antecedent basis in claim 47 for “lactone monomers” (claim 48, line 2). Claim 48 has since been amended to recite “lactones.” No new matter is introduced as a result of this amendment.

The Examiner also states that claim 67 is an improper dependent claim. Claim 67 is now canceled. Hence the Examiner’s rejection of claim 67 is now moot.

**Rejections Under 35 U.S.C. §102(b)**

The Examiner has rejected claims 1-22, 26-29, 32-36, 38, 39, 41, 42, 46-51, 53-56, 61, 63 and 67 under 35 U.S.C. §102(b) as being anticipated by Goldberg et al (WO 01/47368, pages 4-7, 9-14, 19). (¶6)

In making this rejection, the Examiner states that Goldberg et al. discloses chewing gum free of non-biodegradable polymers, including two different biodegradable polymers as claimed by the Applicants, having molecular weights and glass transition temperatures within the Applicants' claimed ranges. Further, the chewing gum of Goldberg et al. also includes conventional ingredients, i.e. resins, softeners, sweeteners, flavoring agents, fillers, coloring agents and film forming agents as claimed by the Applicant and in the amounts claimed by the Applicants. The chewing gum of Goldberg et al. is also may be coated with a syrup, which results in a hard or soft coating, as claimed by the Applicants. The Applicants respectfully traverse this rejection.

As an initial matter, in order for a §102 rejection to be valid, the art cited must teach all limitations required by the claims that define the present invention.

As currently amended, claim 1 requires chewing gum comprising at least two different biodegradable polymers, wherein said at least two different biodegradable polymers have a different glass transition temperature  $T_g$ , wherein at least one of the biodegradable polymers has a glass transition of at least  $+1^{\circ}\text{C}$ , and wherein at least one of the at least two different biodegradable polymers has a glass transition temperature of less than  $0^{\circ}\text{C}$ .

A closer reading of Goldberg et al. disclose a combination of biodegradable and non-biodegradable polymers. Specifically, Goldberg discloses a large number of

copolymers which may be used as a chewing gum base. However, the only actual gum base disclosed in Goldberg et al. (eg. 48) comprises one biodegradable polymer and several non-biodegradable polymers. The only chewing gum disclosed in Goldberg et al. (eg. 49) comprises 26% of the above-described gum base from example 48. Thus, there is no gum disclosed in Goldberg et al. comprising at least two different biodegradable polymers. In addition, Goldberg does not disclose any effects of specific limits for the polymer glass transition temperatures.

In contrast to Goldberg et al., the chewing gum of the present invention comprises at least two different biodegradable polymers having different glass transition temperature  $T_g$ , wherein at least one of the biodegradable polymers has a glass transition of at least  $+1^{\circ}\text{C}$ , and wherein at least one of the at least two different biodegradable polymers has a glass transition temperature of less than  $0^{\circ}\text{C}$  (claim 1).

Since Goldberg et al. do not teach or suggest every element of the present invention as claimed, the Examiner's rejection under 35 U.S.C. §102(b) should be withdrawn.

The Examiner has rejected claims 1, 2, 5, 12, 18, 19, 22-29, 32-44, 46, 47, 50-53 and 63-67 are also rejected under 35 U.S.C. §102(b) as being anticipated by Li et al (6,153,231) or Li et al. (6,613,363). (¶10) In making this rejection, the Examiner states that both Li et al. patents disclose a chewing gum, free of non-biodegradable polymerases claimed by the Applicants, and in the amounts claimed by the Applicants. Further, the chewing gum of Li et al. also includes conventional ingredients, i.e. resins, softeners, sweeteners, flavoring agents, fillers, coloring agents and film forming agents as claimed by the Applicant and in the amounts claimed by the Applicants. The Applicants respectfully traverse this rejection.

A reading of the cited Li et al. patents shows that neither of the Li et al. patents disclose a chewing gum comprising at least two different biodegradable polymers and no ranges or limits for the glass transition temperatures of the polymers is provided. In contrast, for the present application as currently amended, claim 1 requires at least two different biodegradable polymers have a different glass transition temperature  $T_g$ , wherein at least one of the biodegradable polymers has a glass transition of at least  $+1^{\circ}\text{C}$ , and wherein at least one of the at least two different biodegradable polymers has a glass transition temperature of less than  $0^{\circ}\text{C}$ .

Accordingly, since both Li et al. patents do not teach or suggest every element of the present invention as claimed, the Examiner's rejection under 35 U.S.C. §102(b) should be withdrawn.

The Examiner has rejected claims 1, 2, 5, 9-12, 18-53 and 63-67 are also rejected under 35 U.S.C. §102(b) as being anticipated by Grijpma et al (5,672,367). (¶13). In making this rejection, the Examiner argues that Grijpma et al. discloses a chewing gum, free of non-biodegradable polymers, including at least two different biodegradable polymers as claimed by the Applicant, having glass transition temperatures as claimed by the Applicant and in the amounts claimed by the Applicant. The chewing gum of Grijpma et al. also includes conventional ingredients as claimed by the Applicants. The Applicants respectfully traverse this rejection.

Grijpma et al discloses a chewing gum comprising a biodegradable polyester obtained by polymerization of cyclic esters. The  $T_g$  of the biodegradable polyester of Grijpma et al. should be below  $37^{\circ}\text{C}$ . In contrast to the pending application, Grijpma et al. does not disclose a chewing gum comprising at least two different biodegradable polymers having different glass transition temperatures as required in amended claim 1. Accordingly, since Grijpma et al. does not teach or

suggest every element of the present invention as claimed, the Examiner's rejection under 35 U.S.C. §102(b) should be withdrawn.

**Rejections Under 35 U.S.C. §103(a)**

The Examiner has rejected claims 23-25, 30, 31, 37, 40, 43, 52 and 64-66 under 35 U.S.C. §103(a) as being unpatentable over Goldberg et al. (¶7) In making this rejection, the Examiner argues that finding the optimum amount of each component would require nothing more than routine experimentation by one reasonably skilled in the art and that the coating components are conventional chewing gum coating components. The Applicants respectfully traverse this rejection.

Goldberg et al. teaches generally the state-of-the-art assumption that biodegradable polymers must be supplemented with non-biodegradable polymers in order to achieve as successful chewing gum. Goldberg et al. primarily focuses on the amounts and types of (biodegradable and non-biodegradable) monomers which may be used in practicing the technology. Goldberg et al. does not teach or suggest the acceptable amounts of additional components which can be used in the chewing gum. In fact, Goldberg et al. only mentions the use of flavorants and does not give any range or amounts to one should use except for a single example with a defined precise amount of a flavor oil (see Example 49 in Goldberg et al.). There are no teachings or suggestions in Goldberg et al. which suggests an optimum amount of flavorants or other components, especially in view of the fact that the single example shows the use of a flavorant at 1.800% (by weight). In addition, one skilled in the art would not look to Goldberg et al. for limits on flavor concentration ranges since Goldberg et al. uses a mixture of biodegradable & non-biodegradable polymers. This type of

chewing gum has a different moisture content and hence very different properties from the chewing gum of the present invention, which is substantially free of non-biodegradable polymers. Accordingly, there is no teaching suggestion or motivation in Goldberg et al. that would lead one skilled in the art to utilize the concentration ranges of flavorants claimed in the present invention.

The Examiner has also rejected claims 44 and 45 under 35 U.S.C. §103(a), as being unpatentable over Goldberg et al. in view of Li et al. (US 6,153,231, col. 7, lines 60-61). (¶ 8) In making this rejection, the Examiner maintains that it would have been obvious to include a medicinal or pharmaceutical ingredient as an active ingredient in the gum of Goldberg et al., since such an ingredient is a conventional chewing gum component, as evidenced by Li et al. The Applicants respectfully traverse this rejection.

The addition of active ingredients to a gum can dramatically alter the textural properties of that gum, as these ingredients may be, for instance, acidic, basic, a salt, hydrophobic, hydrophilic, or hydrated. Hence, unless the gum bases are identical, there is no way to predict whether or not a chewing gum with added active ingredients will have the desired textural properties for the consumer. Thus, one skilled in the art would understand that there is no teaching, suggestion or motivation in Goldberg et al. for the addition of other substances (besides flavorants) to the chewing gum.

Goldberg et al. is directed to and discloses a chewing gum comprising both biodegradable and non-biodegradable polymers, the use of flavorants for such a gum, and how one skilled in the art may vary the monomers which comprise the chewing gum to achieve the desired textural properties of the gum. Thus, there is no teaching suggestion or motivation in Goldberg et al. in view of Grijpma et al. that would lead one skilled in the art to include active ingredients in the present invention.

The Examiner has rejected claims 54-62 under 35 U.S.C. §103(a), as being unpatentable over Goldberg et al. in view of Meyers (US 5,433,960, cols. 3 & 9-13 and claims 1, 16 and 27) or Li et al. (¶ 9, 12, 15). In making this rejection, the Examiner argues that it would have been obvious to coat the chewing gum in Goldberg et al. with a coating as claimed by the Applicants in order to provide storage stability, as evidenced by Meyers. The Applicants respectfully traverse this rejection.

Goldberg et al. very generally describes a coated gum product (page 9, paragraphs 1 and 2). The gum material of Goldberg et al. is a combination of both degradable and non-biodegradable polymers. The gum material of the present invention is substantially free of non-biodegradable polymers, and the polymers used are within a defined molecular weight range. It is well known to those skilled in the art that the characteristics of a chewing gum made from a mixture of biodegradable and non-biodegradable polymers is substantially different from the characteristics of a chewing gum that is made of biodegradable polymers and is substantially free of non-biodegradable polymers.

Hence, the fact that the chewing gum of Goldberg et al. *might* be coated (note that there is only a general reference to coating a gum tablet in Goldberg et al. with no accompanying examples) would not lead one skilled in the art to coat a chewing gum that is made of biodegradable polymers and is substantially free of non-biodegradable polymers.

It is well known to those skilled in the art that the amount of water contained in a biodegradable chewing gum is critical - too much or too little moisture can have a detrimental impact on the consumer's perceived textural quality of the gum product. There is no teaching, suggestion or motivation in Goldberg et al., in view of either secondary reference that would lead one skilled in the art to conclude that chewing

gum that is made of biodegradable polymers which are substantially free from non-biodegradable polymers could be successfully coated.

Finally, the Examiner has rejected claims 3, 4, 6-11, 13-17, 30, 31 and 45 under 35 U.S.C. §103(a) as being unpatentable over either Li et al. patent and/or Grijpma et al. (¶11, 14). In making this rejection the Examiner argues that finding the optimum molecular weight and glass transition temperature would require nothing more than routine experimentation by one skilled in the art. The Applicants respectfully traverse this rejection.

In Li et al. ('231), gum bases comprising biodegradable elastomers are disclosed. However, no indication is given to the glass transition temperatures as claimed in amended claim 1, that being Li et al. ('231) does not teach or suggest that a combination of a biodegradable polymer with a Tg of at least +1°C with a biodegradable polymer having a Tg below 0°C, i.e., a gum base having two different biodegradable polymers each having different glass transition temperatures, would result in a chewing gum having a texture that is comparable to that of conventional chewing gum. Rather Li et al. ('231) only describes the use of a single elastomer in the gum based which is then combined with conventional gum base ingredients.

In Li et al. ('363), a chewing gum comprising plasticized (D, L lactic acid) is disclosed. Li et al. teaches that the desired texture of the chewing gum is obtained through plasticizing the biodegradable polymer using triacetin as the plasticizer. In contrast, the pending application uses a combination of biodegradable polymers, each with a different Tg to obtain a chewing gum having a texture resembling the texture of a conventional chewing gum. Li et al. ('363) does not teach, suggest or motivate one skilled in the art to combine different biodegradable polymers, each having a



different Tg, and arrive at a chewing gum product having the desired textural qualities of a conventional gum base.

In Grijpma et al., a biodegradable chewing gum comprising biodegradable polyester which is obtained by the polymerization of cyclic esters is disclosed. Grijpma et al. teaches that the Tg of the biodegradable polyester should be below 37°C and that the texture can be modified through the use of plasticizers or softeners, such as lecithin and glycerin. The pending application discloses and claims combining different biodegradable polymers, each having a different Tg in order to obtain a chewing gum product having the desired textural qualities of a conventional gum base. There is no teaching, suggestion or motivation in Grijpma et al. for one skilled in the art to vary the Tg of more than one biodegradable polymer, such that each polymer has a different Tg, and that this would provide a chewing gum having the desired textural qualities of a conventional gum.

Consequently, in view of the above arguments, the rejections under 35 U.S.C. §103(a), have been overcome and should be withdrawn.

### **Double Patenting Rejection**

Claims 1-67 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims: 1-62 of co-pending application 10/472,122; claims 1-54 of co-pending application 10/472,154; claims 1-7 and 10-57 of co-pending application 10/528,927; claims 1-64 of co-pending application 10/529,130; claims 1-20, 22-26, and 28-42 of co-pending application 10/529,133; claims 1-55 of co-pending application 10/529,137; and claims 1, 2, 10, 11, 13-18, 24-26 and 28-54 of co-pending application 11/088,109.

Upon indication of allowable subject matter in this case, Applicants will file the appropriate terminal disclaimers in order to overcome these rejections.

The present application as amended herein, is now in form for allowance and early reconsideration and allowance of the claims, as currently pending, is earnestly solicited.

Respectfully submitted,

ANDERSEN, ET AL.

By Karlyn A. Schnapp  
Karlyn A. Schnapp  
Registration No. 45,558  
Attorney for Applicants

FROST BROWN TODD LLC  
2200 PNC Center  
201 East Fifth Street  
Cincinnati, Ohio 45202  
(513) 651-6865

**CERTIFICATE OF ELECTRONIC FILING**

I hereby certify that this correspondence is being electronically filed with The Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, this 7th day of August 2008.

Eileen Andersen